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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,843	09/09/2003	Mark C. Shults	DEXCOM.8DVC1C1	2133

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EXAMINER	
NASSER, ROBERT L	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/657,843	MARK C. SHULTS ET AL	
	Examiner	Art Unit	
	Robert L. Nasser	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-46 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-46 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/9/03 6/17/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 and 25-43 of copending Application No. 09/916588 in view of Rhodes et al WO/13271. Rhodes shows an alternate sensor design with a domed shaped sensor interface,. As such, it would have been obvious to modify the other invention to use a dome shaped interface, as it is merely the substitution of one known equivalent sensor design for another.

This is a provisional obviousness-type double patenting rejection.

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33-42, 48, 49, and 54-87 of copending Application No. 09/447227 in view of Rhodes et al WO/13271. Rhodes shows an alternate sensor design with a domed shaped sensor interface. As such, it would have been obvious to modify the other invention to use a dome shaped interface, as it is merely the substitution of one known equivalent sensor design for another.

This is a provisional obviousness-type double patenting rejection.

Claims 6-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 and 25-43 of copending Application No. 09916858. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are broader versions of the patented claims, and as such, are covered by the patented claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 6-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33-42, 48, 49, and 54-87 of copending Application No. 09/447227. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are broader versions of the patented claims, and, as such, are covered by the pending claims. . The examiner notes with respect to claims 2, 5, and 37, applicant has not stated that the particular materials used for the layers are for a specific purpose or that the materials used solve a stated problem. Indeed, applicant notes that many materials may be used for each of the layers. As such, it would have been a mere matter of design choice for one skilled in the art to select the proper materials for use. As to the device claims, the method covers providing the device. Hence, it covers the device.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-320 US Patent 6,741,877. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are broader than some of the pending claims, and as such are covered by the pending claims. The examiner notes with respect to claims 2, 5, and 37, applicant has not stated that the particular materials used for the layers are for a specific purpose or that the materials used solve a stated problem. Indeed, applicant notes that many materials may be used for each of the layers. As such, it would have been a mere matter of design choice for one skilled in the art to select the proper materials for use. As to the method claims, it would have been obvious to use the device of the patented claims for the current method.

Claims 39 and 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6001067. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are merely broader versions of the patented claims, and, as such, are covered by the patented claims. .

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 39 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Picha 5706807.

Claims 20-22, and 24-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes et al WO/13271. Rhodes et al has homogeneous enzyme membrane with a outer resistance layer and an inner interference layer that meet the claim language (see pages 7 and 8 and pages 19+).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 29-38, and 40-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al WO 92/13271 in view of Picha. Rhodes shows an implantable glucose sensing device having a housing containing internal electrodes, and a three layer membrane, where in the third layer is an interference layer (see page 7 bottom – page 8 top) which provide a controlled volume to the electrodes, second layer is a enzyme membrane see page 7, and the first layer is a bioprotective layer. The device does not have an angiogenic layer. However, Picha teaches that using an angiogenic layer surrounding an implantable sensor improves the accuracy of the implantable sensor. Hence, it would have been obvious to modify Rhodes et al to use the angiogenic layer, so as to improve the overall accuracy of the device. As such, the angiogenic layer on the bioprotective membrane 12 are a composite membrane. Claims 2, 5, and 37 are rejected in that Rhodes does not teach the material for the

angiogenic layer. However, applicant has not stated that the particular material used for the layers is for a specific purpose or that the material used solves a stated problem. Indeed, applicant notes that many materials may be used for each of the layer. As such, it would have been a mere matter of design choice for one skilled in the art to select he proper material for use. With respect to claim 3, Rhodes teaches a wireless transmitter on page 19. The examiner takes official notice that a radiotelemeter is a known medical transmitter. Claims 29, 30, 32-38 and 40-44 are rejected in that Rhodes teaches all of the features of these claims except the angiogenic layer. Claim 31 is rejected in that the exact oxygen to glucose permeability ratio has not been stated to solve a given problem or to be for a specific reason. As such, the exact ratio would have been a mere matter of design choice for one skilled in the art.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al. The exact oxygen to glucose permeability ratio has not been stated to solve a given problem or to be for a specific reason. As such, the exact ratio would have been a mere matter of design choice for one skilled in the art.

Claims 6-19 would be allowable if the double patenting rejection were overcome.

Claims 45 and 46 would be allowable if the double patenting rejection were overcome and if they were rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 6-16 and 45 define over the art in that in that none of the art has the angiogenic layer and the securing layer. Claims 17-19 define over the art in that none

of the art has the stability layer and the angiogenic layer. Claim 46 defines over the art in that none of the art has the stability layer and the securing layer, as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
9/20/2004

Robert L Nasser

ROBERT L. NASSER
PRIMARY EXAMINER